K092538
pg. 1 of 1

510(k) Summary

MAR - 5 2010

General Information

Submitters Name/Address:	Alure Medical, Inc. 3637 Westwind Boulevard Suite B Santa Rosa, CA 95403
Establishment Registration Number:	3007699483
Contact Person:	Joseph R. Tamayo
Phone Number:	(707) 526-4400 main (707) 526-4466 fax (707) 239-1272 cell
Date Prepared:	18 August 2009

Device Description

Trade Name:	Refine™ Support System
Generic/Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric, (21 CFR 878.3300, Product Code FTL)

Predicate Device Information

Refine™ Support System, K083102

Product Description

The Refine™ Support System consists of a non-absorbable implant and a delivery system. The implant is comprised of a section of mesh with suture tails containing suture barbs for tissue securement. The device and the delivery system are delivered sterile and are for single use only.

Intended Use

The Refine™ Support System is indicated for reinforcement of soft tissue in plastic or reconstructive procedures.

Substantial Equivalence

Indications

Indications for use of the Refine™ Support System are the same as the predicate device and have been substantiated by performance evaluations and comparison studies.

Technological Characteristics

In establishing substantial equivalence to the predicate device, Alure Medical evaluated the materials, technology, and specifications of the subject and predicate device. The technological characteristics are substantially equivalent.

Performance

The Refine™ Support System is considered substantially equivalent in performance to the predicate device. The device conforms to specifications and meets clinical user needs and intended uses. Bench studies and cadaver evaluations substantiate that the Refine™ Support System meets user needs and requirements for performance.

Summary of Safety and Effectiveness

Indications for use, technological characteristics, and performance evaluations of the Refine™ Support System show that the device is substantially equivalent to the predicate device. There are no new risks and concerns regarding safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 5 2010

Alure Medical, Inc.
% Mr. Joseph R. Tamayo
VP of RAQACA
3637 Westwind Boulevard, Suite B
Santa Rosa, California 95403

Re: K092538
Trade/Device Name: Refine™ Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 4, 2010
Received: February 12, 2010

Dear Mr. Tamayo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

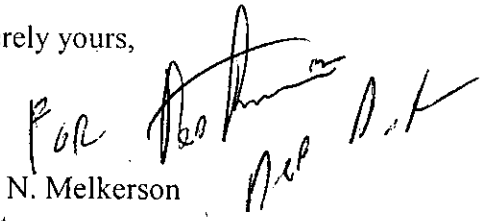
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092538
Pg. 1 of 1

Indications for Use

510(k) Number:

Device Name: Refine™ Support System

Indications for use:

The Refine™ Support System is indicated for reinforcement of soft tissue in plastic or reconstructive procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092538 Page 1 of ____